

REMARKS

In the pending Office Action, Examiner Snow has made several rejections and objections to the present application. The Examiner is respectfully requested to reconsider this application in light of the following remarks and amendments noted above.

Drawing Objections

Several objections to the drawings were given in the Office Action. In each case, it is respectfully submitted that the drawings show the claimed subject matter. Claim 2 recites that “at least one of the first and second ends of the member [that is positioned in the recited body] is chamfered.” An embodiment of the recited member is seen in Figures 1 and 2. The cross-sectional view of Figure 2 shows a slant or chamfer at each of the ends 26, 28, as the claim recites.

Claim 23 recites that “the fixation device allows a predetermined amount of relative motion between the adjacent bony structures during the fusion process.” Figure 9 shows an embodiment of the implant 10 (e.g. that in Figures 1 and 2) between bony structures 66, 68, with a fixation device that allows relative motion, as described in paragraph 0055.

As to claim 24, it is believed that it is proper as it stands. However, to obviate the objection, the claim is being amended as the Examiner proposed.

Finally, the Examiner stated “[a]t least claims 31 and 41, ‘oblique’ is not shown.” Although that comment is not fully understood, it is noted that Figures 1 and 2 show an embodiment of the “oblique” surface of claims 31 and 41. As stated in paragraph 0044 of the application, “the first end 26 may receive load from adjacent bony structures and the second end

28 and side wall of the tapered portion 30 distribute the load to the body 12.” At least the side wall is oblique to end 26.

To summarize, it is respectfully maintained that the drawings show all aspects of the claims. Withdrawal of the objections in the Office Action is respectfully requested.

Rejections under 35 USC 112

The Office Action made two rejections under section 112. First, it was alleged that claim 49 was indefinite, insofar as its language is similar to that of claim 30. Claim 30 was withdrawn by the Examiner, not the Applicant, who maintains that all claims should be examined as explained in a previous filing. On review of the claim, it is agreed that the relevant language of claim 49 is essentially the same as language in claim 30, and thus claim 49 reads on the embodiment of Figure 3. However, that does not make claim 49 indefinite. Its language is capable of interpretation, at least to include the subject matter shown in Figure 3, and thus is not indefinite. (see *Exxon Res. & Eng'g Co. v. U.S.*, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001)).

The second allegation under section 112 was directed at claim 23, and asserted that the specification did not enable “us[ing] a fixation device which allows movement with a fusion device which allows for no movement.” Paragraph 0055 of the specification, among other places, provides the enablement by describing positioning of an implant (e.g. implant 10) between bony structures “desired to be fused together.” Such structures are not already fused, and thus have some capacity for relative movement. The described fixation devices are placed to limit such movement. The process of fusion and healing follows the implantation of the implant, as further described in that paragraph. It would appear from the Examiner’s comments that he

believes that a “fusion device” immediately immobilizes bones, whereas the specification clearly notes that that is not so. Respectfully, claim 23 is properly enabled, and this rejection should be withdrawn.

Rejections over DE 202 05 016 (the “German reference”)

The Office Action proceeded to reject many of the claims as either anticipated by or obvious in view of the German reference. A translation of the German reference was not provided to the Applicant, who has had a translation made and is submitting it with this response. As demonstrated below, the German reference does not anticipate the claims or render them obvious, and it also should be withdrawn as a reference against this application.

Initially, the accompanying declaration of Christopher A. Brown is provided as evidence of prior conception and diligence toward a constructive reduction to practice of this application, on or before the publication date of the German reference. The publication date of the German reference is Thursday, September 18, 2003, and the filing date of the present application is Wednesday, September 24, 2003. As explained in the declaration, a draft of the application was completed prior to September 18, 2003, and thus a conception exists prior to the publication date of the German reference. See MPEP 2138.06. There are three business days (straddling a weekend) between the publication date of the German reference and the filing date of this application. Evidence concerning activities relating to diligence for the days ahead of the filing date, as well as the general level of activity and responsibility for the attorney coordinating the filing, are also given. In these circumstances, prior conception and diligence toward a constructive reduction to practice have been shown. See *Haskell v. Colebourne*, 671 F.2d 1362, 213 USPQ 192, 195 (CCPA 1982) (indicating that six otherwise unexplained days for review

and filing of a draft is sufficiently diligent). Consequently, the German reference should not be applied as the Office Action has done.

Furthermore, it is respectfully noted that the Office Action does not provide a sufficient basis for rejecting all of the claims identified as being anticipated by the German reference. The bottom half of page 6 and the top two lines of page 7 of the Office Action constitute the sole analysis provided for eighteen claims, and that text refers only to claims 1, 6, 26 and 48. It is not conceded that the treatment of those four claims is sufficient, but clearly there is no analysis of record at all of claims 2-5, 10-12, 16-17, 28, 35-36, 47 and 49. Respectfully, it is not possible to develop issues, or to meet the PTO's burden of proof for a rejection, concerning those claims.

As examples of claims that are not anticipated by the German reference, it is noted that the reference does not show the chamfered end(s) of claim 2, the binding agent of claim 3, or a member that stops short of an opposing side as in claim 5. Claims 11 and 12 have been amended to remove certain items from the respective Markush groups. The German reference does not disclose the remaining items. It also plainly rejects use of bone materials for its items 1 and 3, as well as teaching away from use of non-ceramic materials for its "bone replacement material," and from non-radiolucent materials for its item 1. Other features of other claims are also not shown in the German reference.

As to the alleged obviousness of claims 13-15, 21-25, 31-34, 41 and 42, respectfully the Office Action does not make out a proper *prima facie* case of obviousness. The *prima facie* case has three elements: (1) there must be some suggestion or motivation, either in the reference or in knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the

reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See MPEP 2142 (citing cases).

The Office Action acknowledges that the only relied-on reference, the German reference, does not disclose use of bone material, and in fact rejects their use for several reasons. See Translation of German reference, page 2, line 10-page 3, line 17. Thus, the German reference cannot motivate one of ordinary skill to use bone because it actively counsels against that change. One of ordinary skill also cannot glean a reasonable chance of success by using bone, since the German reference's disclosure "makes it possible to eliminate all of the drawbacks" alleged with non-synthetic material, i.e. bone. Respectfully, the German reference directly rebuts any suggestion that one of ordinary skill would have expected the German reference's device to perform equally well with bone materials taught by applicant, as it specifically opines that bone does not work as well as its fully synthetic material. There is no reference of record that would indicate or suggest use of bone with the German reference's device; only the present application suggests use of bone in a body of a fusion implant.

The Office Action may be relying on the personal knowledge of the Examiner, particularly since no secondary reference is cited to provide disclosure of a "fixation device" or "oblique" surfaces, as recited in claims 21-24, 31 and 41-42. If the Office Action indeed relies on personal knowledge of the Examiner, Applicants hereby request an affidavit of the Examiner, pursuant to 37 C.F.R. § 1.104(d)(2), to specifically describe such personal knowledge in order to better develop a full record on which the prosecution can advance. Otherwise, it is respectfully requested that the rejections of claims 21-24, 31 and 41-42 be withdrawn, since it is "never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the

record, as the principal evidence upon which a rejection was based. MPEP 2144.03 (case citation omitted).

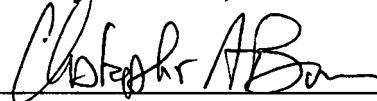
The Office Action also does not address the transfer of load from a bony structure to the recited body, as recited in claim 31. The German reference does not disclose any such transfer, and with the material 3 extending all the way through its item 1 and vertebrae contacting on top and bottom, the material 3 would transmit load between the vertebrae, rather than transferring it to item 1.

Conclusion

It should be understood that this response is not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but is simply provided to move this application to allowance in the most expedient fashion. Applicant reserves the right to later contest positions taken by the Examiner not specifically addressed herein, including arguing claims not specifically argued herein.

For at least the above reasons, withdrawal of the German reference and the rejections based on it is warranted. Applicants respectfully request a Notice of Allowance for the pending claims, and if any further issues remain, the Examiner is invited to call the undersigned.

Respectfully submitted,

By: 

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